



JUL 10 2003

**SUMMARY OF SAFETY AND EFFECTIVENESS****Iontophoresis Electrode**

Date of Summary: 7 April 2003

**A. General Provisions**

Submitter's Name: Iomed, Inc.  
Submitter's Address: 2441 South 3850 West, Suite A  
Salt Lake City, UT 84120-9941  
Contact Person: Curtis Jensen  
Quality and Regulatory Manager  
Classification Name: Iontophoresis Device  
21 CFR 890.5525  
Proprietary Name: RH-900  
Common Name: Iontophoresis Drug Delivery Electrode

**B. Name of Predicate Device(s)**

- Iontophoresis Device K932620  
Iontophoresis Drug Delivery Electrode  
Iomed, Inc. RH-806/GS (TransQ<sup>2</sup>/GS)
- Iontophoresis Device K983484  
Iontophoresis Drug Delivery Electrode  
Empi Dupel B.L.U.E.<sup>TM</sup> (Bi-layer Ultra Electrode)

**C. Device Description**

An iontophoresis device is a device that is intended to use a direct current to introduce ions of soluble salts or other drugs into the body for medical purposes. Iontophoresis technology is based on the principle that an electric potential will cause ions in solution to migrate according to their electrical charges. The quantity and distribution of a drug delivered into and across the skin by iontophoresis is dependent on the charge and molecular weight of the ion, the strength of the electrical current applied, electrode composition, duration of current flow, and numerous other factors.

The RH-900 consists of an active delivery electrode and a passive return electrode. Both electrodes have buffering capability for up to an 80mA-min treatment. These electrodes are designed for a single-patient, one-application use.

This electrode is recommended for use with the Phoresor® Iontophoretic Drug Delivery Systems (Iomed, Inc., Salt Lake City, UT 84120). This system is a 9-volt battery powered, solid state, microprocessor-controlled device that controls current

levels and duration, calculates total charge delivered and monitors current flow and electrode/skin impedance.

The RH-900 electrode consists of a dry, monolithic, impregnated nonwoven polyester fabric liquid containment element designed to be hydrated with an aqueous solution immediately prior to use. It also has a carbon conductive element and an adhesive tape border for skin fixation. All components in contact with the skin are known GRAS materials and/or are listed in the National Formulary.

#### **D. Intended Use**

Iontophoretic drug delivery electrodes are indicated for the administration of soluble salts or other drugs into the body for medical purposes as an alternative to hypodermic injections. They are also indicated for iontophoretic dermal administration of IONTOCAINE® (Lidocaine HCl 2% and Epinephrine 1:100,000 Topical Solution).

#### **E. Drug Delivery and Biocompatibility**

##### **Drug Delivery**

Iontophoretic transport with the RH-900 electrode of both negative and positive charged drugs was compared to transport with currently marketed electrodes in hairless mouse skin *in vitro* by methods described by Petelenz et al., *J Controlled Release* 20 (1992), 55-56 (see 'Performance' section of this document). Model drugs used for these comparisons were radiolabeled dexamethazone sodium phosphate (-) (corticosteroid) and lidocaine hydrochloride (+) (local anesthetic). The testing shows that these model drugs can be comparably delivered using the RH-900.

##### **Biocompatibility**

Primary dermal irritation studies were carried out in rabbits in accordance with FDA regulations for Good Laboratory Practices (GLP) using normal saline. The protocol was designed according to ISO 10993-10:2002, and the device was tested from both positive and negative polarities.

The results of the testing showed that the RH-900 was rated negligible (0.4) when operated from the negative polarity and slight (0.6) from the positive polarity.

These scores are based on the following scale:

- 0.0 to 0.4: negligible
- 0.5 to 1.9: slight
- 2.0 to 4.9: moderate
- 5.0 to 8.0: severe

These scores are comparable to the Iomed, Inc. RH-806/GS (TransQ<sup>2</sup>/GS) marketed electrode. The difference in scales from the testing of the predicate device makes an exact comparison difficult, but it was rated in the lowest range

(mild irritant). Similar scores from the Empi B.L.U.E.<sup>™</sup> are not available for comparison.

Although data is available showing that there are no known health hazards associated with the RH-900 hydratable non-woven material, cytotoxicity test results were not available. Therefore cytotoxicity testing was performed on the hydratable non-woven material following GLP procedures. This is the only material that is used in the RH-900 that has no cytotoxicity data available for it. All other materials are GRAS. Test results show a cytotoxic grade of 2 (on a 0 to 4 scale). This indicates 'mild' reactivity. This meets USP and ISO 10993-10 requirements and shows that all the materials used in the RH-900 are safe to come in limited contact with intact patient skin.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 10 2003

Mr. Curtis Jensen  
Quality and Regulatory Manager  
Iomed, Inc,  
2441 South 3850 West, Suite A  
Salt Lake City, Utah 84120-1191

Re: K031115  
Trade/Device Name: RH-900 Iontophoretic Drug Delivery Electrode  
Regulation Number: 21 CFR 890.5525  
Regulation Name: Iontophoresis device  
Regulatory Class: II and III  
Product Code: KTB, EGJ  
Dated: April 7, 2003  
Received: April 8, 2003

Dear Mr. Jensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act), as long as you comply with all of the Act's requirements relating to drugs labeled or promoted with the devices as described below. You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Our substantially equivalent decision does not apply to drugs for use with your device. Therefore, you may neither label nor promote your device for use with specific drugs other than Iontocaine (Lidocaine HCl 2% and Epinephrine 1:100,000 Topical Solution), nor package drugs with your device prior to FDA having approved the drugs for iontophoretic administration. For information on the requirements for marketing new drugs, you may contact:

Director  
Division of Drug Labeling Compliance (HFD-310)  
Center for Drug Evaluation and Research  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland

As you are aware, iontophoresis devices that are intended to use a direct current to introduce ions of soluble salts or other drugs into the body and induce sweating for use in the diagnosis of cystic fibrosis or for other uses, if the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug, were classified into Class II. An iontophoresis device that is intended to use a direct current to introduce ions of soluble salts or other drugs into the body for medical purposes other than those specified for class II devices is classified into Class III (21 CFR 890.5525). We published our strategy for calling for premarket approval (PMA) applications in the enclosed Federal Register, dated May 6, 1994, and the enclosed memorandum, dated April 19, 1994, and the enclosed Federal Register, dated August 22, 2000.

If you have any questions regarding this letter, you may contact:

Kevin Lee, M.D.  
Food and Drug Administration  
Center for Devices and Radiological Health  
Division of General, Restorative and Neurological Devices  
9200 Corporate Boulevard (HFZ-410)  
Rockville, Maryland 20850  
(301) 594-1296

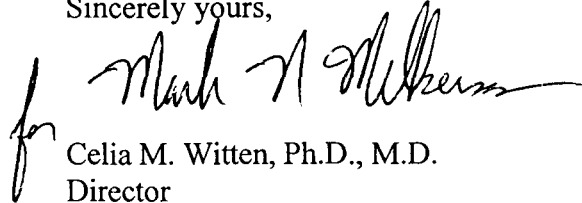
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation, please contact the Office of Compliance at (301) 594- 4659. Also, please note the regulation entitled, "Misbranding by

Page 3 - Mr. Curtis Jensen

reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

for

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosures

## Indications for Use Statement


Applicant: Iomed, Inc.

510(k) Number (if known):

K031115

Device Name: RH-900

Indications For Use: Iontophoretic drug delivery electrodes are indicated for the administration of soluble salts or other drugs into the body for medical purposes as an alternative to hypodermic injections. They are also indicated for iontophoretic dermal administration of IONTOCAINE® (Lidocaine HCl 2% and Epinephrine 1:100,000 Topical Solution).

  
(Division Sign-Off)

Division of General, Restorative  
and Neurological Devices

510(k) Number

K031115

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)